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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,106	01/05/2004	Thomas Lehner	4483-2	1348

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NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,106	LEHNER ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election of Invention of Group I, **Claims 1-6**, in response to the restriction requirement mailed December 13, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 7 is drawn to a method of treatment of Behcet's disease and belongs in Group II. **Claims 7-11** have been withdrawn. **Claims 1-6** are presently under examination.

Priority

The current application filed on January 05, 2004 claims priority to foreign application, UNITED KINGDOM 0314360.9 filed on June 19, 2003.

Preliminary Amendment

The preliminary amendment filed September 09, 2004 has been entered.

Information Disclosure Statement

The IDS filed November 09, 2004 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Claim Objections

Claims 1 and 4 are objected to for not complying with the requirements of 37 CFR 1.821. The claims contain sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, the fails to comply with the requirements of 37 CFR 1.821 through

1.825 for the reason(s) set forth below: Nucleic acid sequences longer than 10 nucleotides and amino acid sequences longer than 4 resides need to be designated with a sequence identifier. Applicants must correct the sequence submissions in the mentioned claims.

Claim 1 cites a polypeptide containing a sequence corresponding to amino acid residues 365-351 of the human heat shock protein HSP 60 or the corresponding residues of the microbial 65kD heat shock protein, the mentioned polypeptides contain more than 4 amino acids and therefore they need to be designated by a SEQ ID No: in compliance with Rule CFR 1.821.

Claim 4 cites a conjugate containing 5 peptide residues the mentioned polypeptide contains more than 4 amino acids and therefore it needs to be designated by a SEQ ID No: in compliance with Rule CFR 1.821.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In **claim 1** the applicants cite polypeptides that "differ by up to and including 4 amino acid alterations (substitutions and or deletion and or insertions); however the only written description that the applicants have provided for the cited polypeptides appears on pages 3-4 of the specification (lines 25-28 and lines 1-4) wherein the applicants state "minor amino acids differences from the above are permissible for conjugation according to the present invention, for example the peptides may differ from each by up to and including 4 amino acid alterations (substitution and/or deletion and or insertion) or one which is extended from any one of the above-mentioned residues at the N-terminus or C-terminus or both with a non-wild-type amino acid residue.

This cannot be considered a sufficient written description of the mentioned peptides since the applicants have not provided a listing of specific amino acids that would be actually substituted, added or inserted. A person of ordinary skill in the art would not be able to anticipate the different peptides cited in the claims without knowledge of their actual amino acid sequences. The applicants have attempted to create a genus without explaining the various species that are incorporated in the genus.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The only adequately described species is the claimed p336-351 linked to

rCTB and no other peptides are disclosed. Accordingly, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not it clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116), As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to undefined substitutions and/or deletions and or insertions. The compound itself is required. See *Fiers* v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF' s were found to be unpatentable due to lack of written description for that broad class.

Claim 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 1** the term "corresponds" allows for a multiplicity of interpretations. For example, corresponds in this case, could mean; an amino acid sequence that has a high degree of homology to the original, a amino acid sequence that comprises the original, or an amino acid sequence that resembles the original in regards to structural integrity. **Claims 2-6** are dependent claims that do not further clarify the independent claim that they depend from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Phipps et al. 2003 (cited in the IDS filed November 09, 2004).

Phipps et al. disclose a polypeptide construct consisting of amino acids 336-352 of the human HSP 60, covalently linked to recombinant cholera toxin B sub-unit (rCTB) (page 225, column 1, lines 7-9).

Phipps et al. also teach that p336-351 linked to rCTB, significantly prevented the development of uveitis when administered orally (page 228, lines 14-15).

Phipps et al. teach further that peptide 336-351 was covalently conjugated to CTB using N-succinimydyl 3-(2-pyridyl)-dithio propionate (Materials and Methods, page 229, column 1, lines 11-13).

Thus Phipps et al. teach all the elements of **claims 1-6** and these claims are anticipated under 35 USC 102(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russell et al. US Patent No: 6,030,624 in view of W. Hu et al. (cited in the IDS filed November 09, 2004).

Russell et al. disclose a recombinant hybrid/chimeric construct comprising the B subunit of chlorea toxin (column 3, lines 36-40).

Russell et al. teach further that here are many potential uses for the technology of the present invention in mucosal vaccine development. The basic method is amenable to almost any other protein antigen that can be cloned and inserted into the construct instead of SBR. For example, a protein antigen from Streptococcus pneumoniae can be used to make a potential vaccine against pneumonia. Similarly, constructs from group A streptococcal proteins or a vaccine against Helicobacter pylori can be prepared using the methodology disclosed in the instant specification. Various applications of the present invention can be incorporated into commercial products, i.e., vaccines for the generation of immune responses that would afford protection against infections, or various modifications of the immune response. These are based on the use of CTA2/B chimeric proteins that include protein segments from a variety of microorganisms, intended for administration orally or intranasally (column 9, lines 27-45).

Russell et al. not disclose a recombinant hybrid/chimeric construct comprising an amino acid sequence corresponding to the amino acid residues 336-351 of the human heat shock protein HSP 60 that is specific for Behcet's disease.

W. Hu et. Al. teach that the amino acid residues 336-351 of the human heat shock protein HSP 60 is specific for Behcet's disease (Discussion, page 2456, column 2, lines 26-29)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct a recombinant hybrid/chimeric polypeptide comprising the B subunit of chlorea toxin and the amino acid residues 336-351 of the human heat

shock protein HSP 60 that is specific for Behcet's disease for the advantages of an enhancing effect on antigen presentation for an effective vaccine for the treatment of Behcet's disease as taught by Russell et al. and W. Hu et al., see Russell et al. at column 3, lines 20-22 and 33-33; column 9, lines 24, 45).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B Mondesi
03-31-05

JON WEBER
SUPERVISORY PATENT EXAMINER